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भारतीय मानक

संवेदनाहारी एवं श्वसन उपस्कर-शंक्वाकर संयोजक

भाग 1 कोन तथा साकेट

(तीसरा पुनरीक्षण)

Indian Standard

ANAESTHETIC AND RESPIRATORY EQUIPMENT— CONICAL CONNECTORS

PART 1 CONES AND SOCKETS

(Third Revision)

ICS 11.040.10

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BUREAU OF INDIAN STANDARDS MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG NEW DELHI 110002

NATIONAL FOREWORD

This Indian Standard (Part 1) (Third Revision) which is identical with ISO 5356-1:1996 'Anaesthetic and respiratory equipment—Conical connectors—Part 1: Cones and sockets' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in1974 and revised in 1985 to incorporate the requirements of conical fittings for to-and-fro carbon dioxide absorber (water type) for use with anaesthetic apparatus and to include the requirements for non-metallic materials for various components. Consequent upon the publication of ISO 5356-1:1987 the standard was revised as a dual number standard identical to ISO 5356-1:1987 to align its requirements with the latest international practices. As a result of this revision, the sequence of joint fittings and typical arrangement of equipments for different types of anaesthetic apparatus covered earlier were deleted.

Its third revision has been undertaken to incorporate the modifications effected in the second edition of ISO 5356-1 brought out in 1996.

In clinical practice, several breathing attachments used in anaesthetic and respiratory equipment may have to be joined together to provide a suitable breathing system. Items of medical equipment, such as, a humidifier or a spirometer, are often incorporated into the breathing system which may also be connected to an anaesthetic gas scavenging system. Connections for these purposes are usually cone and socket joints and a lack of standardization of these connections has given rise to problems of interchangeability when connecting equipment made by different manufacturers. This standard specifies particular requirements and dimensions for conical connectors used in anaesthetic and respiratory equipment.

An important consideration is that conical connections should be secure but nevertheless disconnectable by the operator. The use of connectors meeting the requirements of this standard will not necessarily prevent them being disconnected accidentally.

Annex A includes a figure and a table detailing plug and ring test gauges that are used to check conical connectors made of materials other than metal. Annex E includes a figure and table detailing plug and ring test gauges that may be used to check metal conical connectors.

Figure 1, detailing the dimensions and tolerances of metal conical connectors, has been prepared in accordance with ISO 3040.

Annexes A to D form an integral part of this standard. Annexes E to G are for information only.

The text of International Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

Indian Standard

ANAESTHETIC AND RESPIRATORY EQUIPMENT— CONICAL CONNECTORS

PART 1 CONES AND SOCKETS (Third Revision)

1 Scope

This part of ISO 5356 specifies dimensional and gauging requirements for cones and sockets intended for connecting anaesthetic and respiratory equipment, e.g. in breathing systems, anaesthetic gas scavenging systems and vaporizers.

This part of ISO 5356 gives requirements for the following conical connectors:

- 15 mm and 22 mm sizes intended for general use in breathing systems;
- 22 mm latching connectors (including performance requirements);
- 23 mm size intended for use with vaporizers; this size is unsuitable for use in breathing systems;
- 30 mm size intended for the connection of a breathing system to an anaesthetic gas scavenging system.

This part of ISO 5356 does not specify the medical devices and accessories on which these connections are to be provided.

Requirements for the application of conical connectors are not included in this part of ISO 5356, but are or will be given in particular International Standards for specific medical devices and accessories.

NOTE — Requirements for screw-threaded weight-bearing conical connectors are specified in ISO 5356-2.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5356. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5356 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 4135:1995, Anaesthesiology — Vocabulary.

ISO 5367:1991, Breathing tubes intended for use with anaesthetic apparatus and ventilators.

IEC 601-1:1988, Medical electrical equipment — Part 1: General requirements for safety.

3 Definitions

For the purposes of this part of ISO 5356, the definitions given in ISO 4135 and the following definition apply.

3.1 22-mm latching connector: Female connector for engagement with a male conical connector of 22-mm size complying with this part of ISO 5356, and which has a feature to reduce the possibility of accidental disconnection.

4 Conical connectors made of metal

4.1 General requirements

The dimensions of conical connectors made of metal including those made of composite materials in which the mating surfaces are metal, shall be as shown in figures 1 and 2 and table 1.

NOTES

- 1 See annex E for dimensions of plug and ring gauges for the connectors.
- 2 Conical connectors of 30 mm size are intended for use for the connection of a breathing system to an anaesthetic gas scavenging system.

4.2 Additional requirements for conical connectors of 22 mm size

- **4.2.1** Male conical connectors of 22 mm size, with the exception of those intended for connection to a face mask, shall incorporate the recess as shown in figure 2 a).
- **4.2.2** All male connectors to which it is intended to attach a face mask shall incorporate a shoulder or equivalent construction as shown in figure 2 b).
- **4.2.3** If a circumferential groove or grooves are incorporated in the surface of such a male conical connector, the total width of the groove or grooves at the surface shall not exceed 8 mm.

5 Conical connectors made of materials other than metal

5.1 General requirements

Conical connectors made of materials other than metal shall meet the following requirements when they are type-tested with gauges having dimensions as shown in figure A.1 and table A.1.

- a) Conical connectors made of materials other than metal shall meet the dimensional requirements in figure 1 and table 1, with the exception that dimensions A and B and ratio F may vary from those shown.
- b) When the connector is engaged in the appropriate plug or ring test gauge shown in figure A.1 and table A.1, by applying an axial force of (35 ± 3.5) N for 15 mm connectors and (50 ± 5) N for 22 mm and 30 mm connectors and, while maintaining the same force, rotating the connector up to 20°, its leading edge shall lie between the minimum and maximum diameter steps of the gauge. The connectors and gauges shall be maintained at a temperature of (20 ± 3) °C during the test.

NOTE — Because connectors made from plastics materials, for example polyamide, polyacetal, polycarbonate, polysulfone, etc., may vary greatly in their physical characteristics, it is not considered practicable to specify their dimensions; for this reason, gauging requirements have been included. It is also considered impracticable to generalize on matters such as cold flow and thermal instability, as well as possible changes in physical characteristics, contact with solvents, etc.

It is the responsibility of the manufacturer to ensure that adequate tests have been carried out to prove as far as possible that the particular materials chosen for the connectors are suitable.

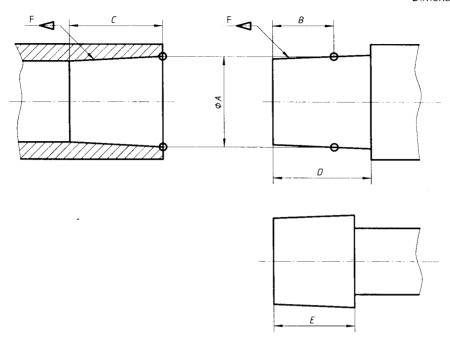
5.2 Additional requirements for conical connectors of 22 mm size

The requirements given in 4.2 apply.

6 22-mm latching connectors

- **6.1** 22-mm latching connectors shall engage with the 22-mm male connector with a recess as specified in figure 2 a).
- 6.2 When tested in accordance with annex B, the engaged connection shall not become disconnected.
- **6.3** When tested in accordance with annex C, the leakage rate from the engaged connectors shall not exceed 5 ml/min (corrected to 20 °C and 101,3 kPa).
- **6.4** After being subjected to the procedure described in annex D, the 22-mm latching connector shall still meet the requirements specified in 6.1, 6.2 and 6.3.
- **6.5** 22-mm latching connectors intended for re-use shall meet the requirements specified in 6.1, 6.2, 6.3 and 6.4 after being subjected to the cleaning, disinfection or sterilization procedures specified in IEC 601-1:1988, subclause 44.7.

Dimensions in millimetres



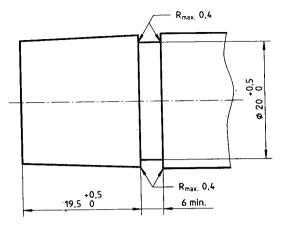
NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should be not less than 0,5 mm and not more than 0,8 mm.

Figure 1 — Conical connectors made of metal

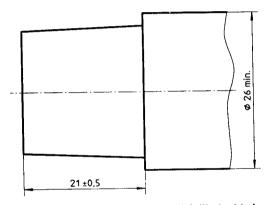
Table 1 — Conical connectors made of metal — Dimensions

	A	В	С	D	Е	F
Connector size	mm	mm	Minimum length of taper mm	Clearance to shoulder (if present) mm	Length to taper	
15 mm	15,47 ± 0,04	10	16	16 min.	14,5 min.	1:40
_22 mm	22,37 ± 0,04	15	21	see figure 2	see figure 2	1:40
23 mm	23,175 ± 0,02	13	18	18 min.	15 min.	1:36
30 mm	30,9 ± 0,05	14	18	18 min.	14 min.	1:20

Dimensions in millimetres



a) Connector intended for breathing attachment (with recess)



b) Connector intended for face mask (with shoulder)

NOTE — Circumferential grooves may be incorporated on the surface of the male cone, if required (see 4.2.3).

Figure 2 — Conical connectors of 22-mm size made of metal — Supplementary dimensions

Annex A

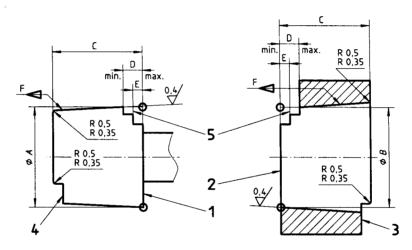
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Plug and ring test gauges for conical connectors made of materials other than metal

A.1 General

Figure A.1 and table A.1 give details of plug and ring gauges for use in checking conical connectors made of materials other than metals.

Dimensions in millimetres Surface roughness values in micrometres



- 1 Face A
- 2 Face B
- 3 Step to check mating gauges ground flush to face A
- 4 Step to check mating gauges ground flush to face B
- 5 Basic steps

NOTE - Basic and mating gauge steps are optional.

Figure A.1 — Plug and ring test gauges for conical connectors made of materials other than metal

Table A.1 — Plug and ring test gauges for conical connectors made of materials other than metal — Dimensions

Connector size	A mm	<i>B</i> mm	<i>C</i> mm	<i>D</i> mm	<i>E</i> mm	F	Tolerance on taper per unit of length on diameter mm
15 mm	15,525 ± 0,005	15,165 ± 0,005	14,5 ± 0,005	4,3 ± 0,005	2,2 ± 0,005	1:40	0,025 ± 0,000 2
22 mm	22,425 ± 0,005	21,94 ± 0,005	19,5 ± 0,005	5,2 ± 0,005	2,2 ± 0,005	1:40	0,025 ± 0,000 2
30 mm	30,98 ± 0,005	30,12 ± 0,005	15 ± 0,005	3,1 ± 0,005	1,6 ± 0,005	1:20	0,050 ± 0,000 2

Annex B

(normative)

Test for security of engagement of 22-mm latching connector to male conical connector

- **B.1** Condition a male 22-mm conical connector complying with figure 2 a) and the 22-mm latching conector for 1 h at a temperature of (35 ± 3) °C and relative humidity of at least 80 %, and carry out the test under the same conditions.
- **B.2** Engage the 22-mm latching connector with the male connector in accordance with the manufacturer's instructions.
- **B.3** After 1 min of engagement without activation of any disengagement mechanism, apply for 10 s an axial separation force of (50 ± 5) N and, unless the 22-mm latching connector permits free radial rotation, also apply a torque of (25 ± 5) N·cm at a rate not exceeding 20 N·s⁻¹.
- **B.4** Observe whether the assembled connectors become disconnected.

NOTE — Examples of suitable apparatus that can be used to test security of engagement, together with a more detailed test procedure, are given for information in annex F.

Annex C

(normative)

Test for leakage from 22-mm latching connectors

- **C.1** Take the engaged male conical connector and 22-mm latching connector that have been tested as described in annex B and condition them at (35 ± 3) °C.
- **C.2** Using air, apply an internal static pressure of (8 ± 0.5) kPa above ambient to the assembly and determine the leakage rate from the assembly, e.g. by pressure drop or volumetric methods.

Annex D

(normative)

Drop procedure for 22-mm latching connectors

- **D.1** Condition a male conical connector complying with figure 2 a) and the 22-mm latching connector for 1 h at a temperature of (20 ± 3) °C and relative humidity of at least 80 %, and carry out the test under the same conditions.
- **D.2** Engage the 22-mm latching connector with the male conical connector in accordance with the manufacturer's instructions. Attach the male conical connector to a breathing tube complying with ISO 5367 and having a length of 2 m.
- **D.3** Attach the opposite end of the breathing tube to a point 1 m above a 50-mm thick hardwood board (e.g. hardwood having a density greater than 700 kg/m³) standing on a rigid base (e.g. a concrete block).
- **D.4** Raise the engaged connectors to a point 1 m above the board and 2 m distant from the other end of the breathing tube and release them so that they fall onto the hardwood board. Repeat this five times.
- **D.5** Proceed with desired test.

Annex E

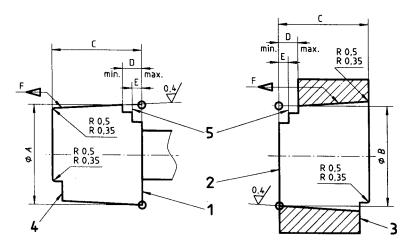
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Plug and ring test gauges for conical connectors made of metal

E.1 General

Figure E.1 and table E.1 give, for information, details of plug and ring test gauges that may be used to check metal conical connectors.

Dimensions in millimetres Surface roughness values in micrometres



- 1 Face A
- 2 Face B
- 3 Step to check mating gauges ground flush to face A
- 4 Step to check mating gauges ground flush to face B
- 5 Basic steps

NOTE — Basic and mating gauge steps are optional.

Figure E.1 — Plug and ring test gauges for conical connectors made of metal

Table E.1 — Plug and ring test gauges for conical connectors made of metal — Dimensions

Connector size	A mm	B mm	<i>C</i> mm	<i>D</i> mm	<i>E</i> mm	F	Tolerance on taper per unit of length on diameter mm
15 mm	15,51 ± 0,005	15,18 ± 0,005	14,5 ± 0,005	3 ± 0,005	1,6 ± 0,005	1:40	0,025 ± 0,000 2
22 mm	22,41 ± 0,005	21,955 ± 0,005	19,5 ± 0,005	3 ± 0,005	1,6 ± 0,005	1:40	0,025 ± 0,000 2
23 mm	23,195 ± 0,003	22,794 ± 0,003	16 ± 0,005	1,33 ± 0,005	0,72 ± 0,005	1:36	0,0278 ± 0,000 2
30 mm	30,95 ± 0,005	30,15 ± 0,005	17 ± 0,005	1,9 ± 0,005	1 ± 0,005	1:20	0,050 ± 0,000 2

Annex F

(informative)

Suggested apparatus and methods for testing the security of engagement of 22-mm latching connectors

F.1 Method 1 — Bench-mounted test equipment

F.1.1 Apparatus

A typical bench-mounted apparatus for testing the security of engagement of 22-mm latching connectors is shown in figure F.1. The male test piece should be a 22-mm male conical connector dimensioned as shown in figure 2 a) but with all the tolerances reduced to \pm 0,005 mm and a surface finish of 0,4 μ m.

NOTE — There are a number of methods for applying the test forces, and figure F.1 is illustrative of only one approach. Other methods include the use of gravity loading by weights or liquid containers.

The essential features of the apparatus should ensure that the tensile force can be applied in a truly axial direction and that torque can be applied without changing the tensile force. To minimize the effects of the friction of the apparatus, the tensile force should be measured directly between the 22-mm latching connector and the male test piece.

F.1.2 Procedure

- **F.1.2.1** Secure the 22-mm latching connector to be tested in the self-centring holder of the apparatus (F.1.1), ensuring that the method of securing the 22-mm latching connector does not deform the section(s) that are intended to engage with the male test piece.
- **F.1.2.2** Condition the 22-mm latching connector and the apparatus at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % for 1 h.
- NOTE If a number of 22-mm latching connectors are to be tested, some may be conditioned at the required temperature and relative humidity without being secured to the apapratus, provided that they are conditioned again for at least 5 min after being secured to the apparatus.
- **F.1.2.3** Engage the 22-mm latching connector with the male test piece in accordance with the manufacturer's instructions.
- **F.1.2.4** After 1 min, attach the force-measuring device and apply an axial separation force at a rate not exceeding $20 \text{ N} \cdot \text{s}^{-1}$ until a force of $(50 \pm 5) \text{ N}$ is being applied. Maintain this force for 10 s without activating any disengagement mechanism, and observe whether the engaged 22-mm latching connector and male test piece become disconnected.
- **F.1.2.5** Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N cm or rotate the male test piece through an angle of 20° , whichever occurs first. Maintain this torque or position for 10 s and observe whether the engaged 22-mm latching connector and male test piece become disconnected.

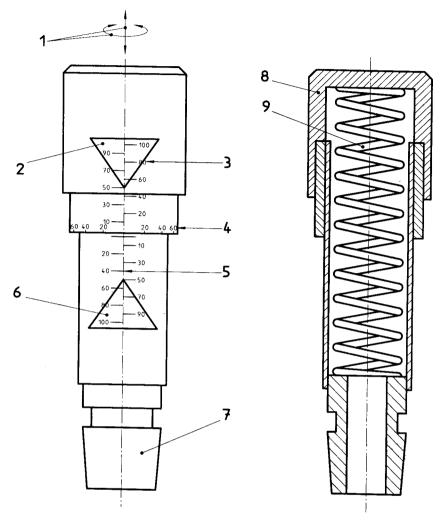
F.2 Method 2 — Hand-held test equipment

F.2.1 Apparatus

A typical hand-held apparatus for testing the security of engagement of 22-mm latching connectors is shown in figure F.2.

F.2.2 Procedure

- **F.2.2.1** Condition the 22-mm latching connector and the apparatus (F.2.1) at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % for 1 h.
- **F.2.2.2** Engage the 22-mm latching connector with the male test piece on the apparatus in accordance with the manufacturer's instructions.
- **F.2.2.3** After 1 min, manually apply an axial separation force at a rate not exceeding 20 N·s⁻¹ until a force of (50 ± 5) N is being applied. Maintain this force for 10 s without activation of any disengagement mechanism, and observe whether the engaged 22-mm latching connector and male test piece become disconnected.
- **F.2.2.4** Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N cm or rotate the male test piece through an angle of 20° , whichever occurs first. Maintain this torque or position for 10 s, and observe whether the engaged 22-mm latching connector and male test piece become disconnected.
- F.2.2.5 Repeat the procedure described in clause F.2.2.4 with the torque applied in the opposite direction.



a) External view

- 1 Appplication of torque or push or pull by hand
- 2 Area of scale indicating acceptable pull and twist forces
- 3 Pull-force scale
- 4 Torque scale
- 5 Push-force scale
- 6 Area of scale indicating acceptable push and twist forces
- 7 22-mm male test piece

NOTE — Torque and force scales precalibrated using apparatus in figure F.1.

Figure F.2 — Apparatus for testing the security of engagement of 22-mm latching connectors (Method 2 — Hand-held)

- 8 Knob
- 9 Coil spring fixed at both ends

Annex G

(informative)

Bibliography

[1] ISO 3040:1990, Technical drawings — Dimensioning and tolerancing — Cones.

(Continued from second cover)

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for the editions indicated:

International Standard	Corresponding Indian Standard	Degree of Equivalence
ISO 4135:1995	IS 13200:1993 Anaesthesiology — Vocabulary	Technically equivalent
ISO 5367:1991	IS 11363:1994 Tubes, breathing, for anaesthetic apparatus and ventilators	do
IEC 60601-1(1988)	IS 13450 (Part 1):1994 Medical electrical equipment: Part 1 General requirements for safety	Identical

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2:1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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Amendments Issued Since Publication

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